



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/645,834	08/20/2003	Mattias Karlsson	58072 (447137)	7644
21874 7590 08/06/2007 EDWARDS ANGELL PALMER & DODGE LLP P.O. BOX 55874 BOSTON, MA 02205			EXAMINER BEISNER, WILLIAM H	
			ART UNIT 1744	PAPER NUMBER
			MAIL DATE 08/06/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/645,834

Applicant(s)

KARLSSON ET AL.

Examiner

William H. Beisner

Art Unit

1744

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 22 May 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-8, 11-18, 21-30, 87-89, 93-95, 97-101 and 109-116 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-8, 11-18, 21-30, 87-89, 93-95, 97-101 and 109-116 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *Drawings*

1. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, all of the claimed structures encompassed by claims 1-8, 11-18, 21-30, 87-89, 93-95, 97-101 and 109-116 must be shown or the feature(s) canceled from the claim(s). No new matter should be entered. Note only Figure 6 of the instant drawings appears to be related to the instant claims being examined. This figure merely depicts a substantially planar substrate with a nonplanar element. The figures are completely devoid of any showing of a conducting element (fixed or movable), fluid source or mechanism, a cell chamber, and/or microchannels in combination with the structure shown in Figure 6.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will

Art Unit: 1744

be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-8, 11-18, 21-30, 87-89, 93-95, 97-101 and 109-116 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is indefinite for several reasons. First it is not clear how the additionally recited “one channel”, “fluid source”, “cell chamber” and “at least one nonplanar element” structurally cooperate with the previously positively recited elements of the claim. Note is the second recited “at least one nonplanar element” the same as the first recited nonplanar element or an additional element. Clarification and/or correction is requested. Also which of the two recited “at least one nonplanar elements” is an integral part of the substantially planar substrate? The same holds true for independent claims 93, 94 and 99. Also, how does the “protruded surface” of these claims differ from the “at least one nonplanar element” further recited, if at all?

Claims 2-8, 11-18, 21-30, 87-89, 94, 97, 98, 100, 101 and 109-116 are indefinite in view of their dependency from claims 1, 93, 94 or 99.

In claim 24, how does the recited “cell chamber” differ from that previously recited in claim 1, if at all?

Art Unit: 1744

Claim 109 is indefinite because it is not clear if the "a cell chamber" recited in this claim is the same or different from that recited in claim 1.

***Claim Rejections - 35 USC § 102***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 1-6, 11-18, 21-30, 87-89, 93-95, 99-101 and 109-116 are rejected under 35 U.S.C. 102(a) or (e) as being anticipated by Baumann et al.(US 6,368,851).

With respect to claim 1, the reference of Baumann et al. discloses a substantially planar substrate (4) (See Figure 22) in communication with at least one conducting element (18), wherein the substantially planar substrate (4) comprises at least one nonplanar element (20) for establishing and/or maintaining electrical communication with a cell (3), at least one channel (38) in communication with a fluid source (See column 16, line 28, to column 17, line 2), at least one cell chamber (2) (See Figure 17), and at least one nonplanar element (20) exposed to fluid flow from a fluid source (See column 16, line 67, to column 17, line 2), and wherein the nonplanar element (20) is an integral part of the substantially planar substrate (4).

Art Unit: 1744

With respect to claim 2, the nonplanar element (20) includes a raised portion (See Figure 22) having an opening (16) in which a conducting fluid (nutrient medium) is disposed.

With respect to claim 3, the conducting fluid is in electrical communication with a conducting element (6).

With respect to claim 4, at least a portion of the nonplanar element (20) comprises a conducting surface (6).

With respect to claim 5, the nonplanar element (20) comprises a nonconducting surface (9).

With respect to claim 6, at least a portion of the substrate comprises a polymer (See column 13, lines 1-2).

With respect to claims 11 and 12, the nonplanar element (20) can be exposed to a fluid flow from a fluid source (See Figure 22 and column 16, lines 27-39).

With respect to claims 13 and 14, the surface of the nonplanar element is “nonplanar”, “protruding” and/or “rounded” (See Figure 22).

With respect to claims 15 and 16, the structure defining channel (38) is considered to meet the claim language of a capillary or micropipette.

With respect to claim 17, the nonplanar element (20) is considered to have a nonplanar surface (32) (See Figure 22).

With respect to claim 18, the surface (32) is protruding.

With respect to claim 21, the device includes a voltage source (12).

With respect to claim 22, in the absence of further positively recited structure, the device is considered as being capable of maintaining a seal as required of the instant claim language.

Art Unit: 1744

With respect to claim 23, the nonplanar element (20) is conical (See Figure 22).

With respect to claim 24, the device includes a cell chamber (See Figure 18 and column 13, line 55, to column 14, line 11) and a plurality of nonplanar elements (See Figure 17).

With respect to claim 25, fluid can enter the cell chamber through passage (38) in the substrate.

With respect to claim 26, a surface of the nonplanar element can be rendered hydrophilic (See column 8, lines 21-29).

With respect to claims 27 and 28, the device includes a fluid controlling mechanism (micropump) (See column 16, lines 28-39).

With respect to claims 29 and 30, in the absence of further positively recited structure, the surface of the nonplanar element is considered to be structurally the same as that of a surface which has been chemically washed or exposed to chemical deposition.

With respect to claims 87-89, the nonplanar element (20) is a portion of wall (4) which is a portion of a cell chamber (See Figure 18).

With respect to claim 93, the reference of Baumann et al. discloses a substantially planar substrate (4) (See Figure 22) comprising a cell chamber (See Figure 18) comprising a protruded surface (20) defining an opening (32) in fluid communication with an electrode compartment (38), wherein the cell chamber is adapted to be in fluid communication with an external device (See column 16, line 28, to column 17, line 2), wherein one or more of the communications comprise microchannels (38), and at least one nonplanar element (20) exposed to fluid flow from a fluid source (See column 16, line 67, to column 17, line 2), wherein the nonplanar element is an integral part of the substantially planar substrate.

With respect to claim 94, the reference of Baumann et al. discloses a substantially planar substrate (4) (See Figure 22) comprising a reservoir in fluid communication with a cell chamber (See column 16, line 28, to column 17, line 2) comprising a protruded surface (20) defining an opening (32) communicating with an electrode compartment (38), wherein one or more of the communications comprise microchannels (38) and at least one nonplanar element (20) exposed to fluid flow from a fluid source (See column 16, line 67, to column 17, line 2), wherein the nonplanar element is an integral part of the substantially planar substrate.

With respect to claim 95, the protruded surface includes a column shape (See Figure 22).

With respect to claim 97, the portion of the wall includes microchannel (38).

With respect to claim 98, the protruded surface defining an opening includes a microchannel (38).

With respect to claim 99, the reference of Baumann et al. discloses a system for providing fluid flow for establishing and maintaining an electrically resistant seal between a cell and a conducting element comprising a substantially planar substrate (4) (See Figure 22) comprising a protruded surface (20) defining an opening (32) in fluid communication with an electrode compartment (38), wherein the substrate (4) is adapted to be in fluid communication with an external device (See column 16, line 28, to column 17, line 2), at least one cell chamber (See Figure 18), and at least one nonplanar element (20) exposed to fluid flow from a fluid source (See column 16, line 67, to column 17, line 2), wherein the nonplanar element is an integral part of the substantially planar substrate.

With respect to claim 100, the device includes a conducting element (6 or 18).



Art Unit: 1744

With respect to claim 101, the conducting element can be movable relative to the fluid source (See column 15, lines 59-63).

With respect to claim 109, see the discussion of claims 93, 94 and 99 above.

With respect to claims 110-114, the device of Baumann et al. includes nonoscale structures (22) to enhance the seal of the cell to the nonplanar element.

With respect to claim 115, the nonplanar element (20) is conical or pyramidal in shape (See Figure 22).

With respect to claim 116, when using a plurality of sensing elements as shown in Figure 17, the device would include a plurality of microchannels (38).

### ***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Art Unit: 1744

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claim 1-3, 5, 11-18, 21-23, 25, 27-30, 87-89, 93-95, 97-101, 109-113, 115 and 116 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stett et al.(US 2003/0153067 or WO 02/03058).

With respect to claim 1, the reference of Stett et al. discloses a substantially planar substrate (31) (See Figure 2) in communication with at least one conducting element (43), wherein the substantially planar substrate (31) comprises at least one nonplanar element (37) for establishing and/or maintaining electrical communication with a cell (11), at least one channel (45) in communication with a fluid source (See Figure 2), at least one cell chamber (16) (See Figure 2), and at least one nonplanar element (37) exposed to fluid flow from a fluid source (12 or 19).

While the reference discloses that nonplanar element (37) is removable, claim 1 differs by reciting that the nonplanar element is integral with the substrate.

However, in the absence of a showing of criticality and/or unexpected results, it would have been merely an obvious matter in design choice to provide the nonplanar element (37) of

Art Unit: 1744

the primary reference as an integral structure of the substrate when replacement of the element is not required. Note “that the use of a one piece construction instead of the structure disclosed in [the prior art] would be merely a matter of obvious engineering choice.” In re Larson, 340 F.2d 965, 968, 144 USPQ 347, 349 (CCPA 1965).

With respect to claim 2, the nonplanar element (37) includes a raised portion (See Figure 2) having an opening in which a conducting fluid is disposed.

With respect to claim 3, the conducting fluid is in electrical communication with a conducting element (43).

With respect to claim 5, the nonplanar element (37) comprises a nonconducting surface (38).

With respect to claims 11 and 12, the nonplanar element (37) can be exposed to a fluid flow from a fluid source (42).

With respect to claims 13 and 14, the surface of the nonplanar element is “nonplanar”, “protruding” and/or “rounded” (See Figure 2).

With respect to claims 15 and 16, the structure defining channel (37) is considered to meet the claim language of a capillary or micropipette.

With respect to claim 17, the nonplanar element (37) is considered to have a nonplanar surface (38) (See Figure 2).

With respect to claim 18, the surface (38) is protruding.

With respect to claim 21, the device includes a voltage source (28).

With respect to claim 22, in the absence of further positively recited structure, the device is considered as being capable of maintaining a seal as required of the instant claim language.

With respect to claim 23, the nonplanar element (37) is conical (See Figure 2).

With respect to claim 25, fluid can enter the cell chamber through passage (41 or 45) in the substrate.

With respect to claims 27 and 28, the device includes a fluid controlling mechanism (micropump) (42).

With respect to claims 29 and 30, in the absence of further positively recited structure, the surface of the nonplanar element is considered to be structurally the same as that of a surface which has been chemically washed or exposed to chemical deposition.

With respect to claims 87-89, the nonplanar element (37) is a portion of wall (31) which is a portion of a cell chamber (See Figure 2).

With respect to claim 93, the reference of Stett et al. discloses a substantially planar substrate (31) (See Figure 2) comprising a cell chamber (16) comprising a protruded surface (37) defining an opening (38) in fluid communication with an electrode compartment (41), wherein the cell chamber is adapted to be in fluid communication with an external device (12 or 19), wherein one or more of the communications comprise microchannels (45), and at least one nonplanar element (37) exposed to fluid flow from a fluid source (12 or 19).

While the reference discloses that nonplanar element (37) is removable, claim 93 differs by reciting that the nonplanar element is integral with the substrate.

However, in the absence of a showing of criticality and/or unexpected results, it would have been merely an obvious matter in design choice to provide the nonplanar element (37) of the primary reference as an integral structure of the substrate when replacement of the element is not required. Note "that the use of a one piece construction instead of the structure disclosed in

Art Unit: 1744

[the prior art] would be merely a matter of obvious engineering choice.” In re Larson, 340 F.2d 965, 968, 144 USPQ 347, 349 (CCPA 1965).

With respect to claim 94, the reference of Stett et al. discloses a substantially planar substrate (4) (See Figure 22) comprising a reservoir (12 or 19) in fluid communication with a cell chamber (16) comprising a protruded surface (37) defining an opening (38) communicating with an electrode compartment (41), wherein one or more of the communications comprise microchannels (45) and at least one nonplanar element (37) exposed to fluid flow from a fluid source (12 or 19).

While the reference discloses that nonplanar element (37) is removable, claim 94 differs by reciting that the nonplanar element is integral with the substrate.

However, in the absence of a showing of criticality and/or unexpected results, it would have been merely an obvious matter in design choice to provide the nonplanar element (37) of the primary reference as an integral structure of the substrate when replacement of the element is not required. Note “that the use of a one piece construction instead of the structure disclosed in [the prior art] would be merely a matter of obvious engineering choice.” In re Larson, 340 F.2d 965, 968, 144 USPQ 347, 349 (CCPA 1965).

With respect to claim 95, the protruded surface includes a column shape (See Figure 2).

With respect to claim 97, the portion of the wall includes microchannel (41).

With respect to claim 98, the protruded surface defining an opening includes a microchannel (41).

With respect to claim 99, the reference of Stett et al. discloses a system for providing fluid flow for establishing and maintaining an electrically resistant seal between a cell and a

Art Unit: 1744

conducting element comprising a substantially planar substrate (31) (See Figure 2) comprising a protruded surface (37) defining an opening (38) in fluid communication with an electrode compartment (41), wherein the substrate (31) is adapted to be in fluid communication with an external device (12 or 19), at least one cell chamber (16), and at least one nonplanar element (37) exposed to fluid flow from a fluid source (12 or 19).

While the reference discloses that nonplanar element (37) is removable, claim 99 differs by reciting that the nonplanar element is integral with the substrate.

However, in the absence of a showing of criticality and/or unexpected results, it would have been merely an obvious matter in design choice to provide the nonplanar element (37) of the primary reference as an integral structure of the substrate when replacement of the element is not required. Note "that the use of a one piece construction instead of the structure disclosed in [the prior art] would be merely a matter of obvious engineering choice." In re Larson, 340 F.2d 965, 968, 144 USPQ 347, 349 (CCPA 1965).

With respect to claim 100, the device includes a conducting element (43).

With respect to claim 101, the conducting element can be movable relative to the fluid source (See Figures 4-6).

With respect to claim 109, see the discussion of claims 93, 94 and 99 above.

With respect to claims 110-113, the reference of Stett et al. discloses the use of non-planar or protruded surface (35) for enhancing the seal of the cell.

With respect to claims 114 and 115, in the absence of a showing of criticality and/or unexpected results, it would have been obvious to one of ordinary skill in the art to optimize the

Art Unit: 1744

shape of the non-planar elements while maintaining their required functions of sealing with the cell.

With respect to claim 116, the reference of Stett et al. discloses a plurality of microchannels communicated with sources (19) (See Figure 1) and microchannels (45 and 33).

10. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Baumann et al.(US 6,368,851) or Stett et al. (US 2003/0153067 or WO 02/03058) in view of Klemic et al. (Biosensor and Bioelectronics).

The references of Baumann et al. and Stett et al. have been discussed above.

While both the references of Baumann et al. and Stett et al. disclose that the substrates can be made of glass or plastic, the references are silent with respect to the use of an elastomeric polymer.

The reference of Klemic et al. discloses that it is known in the art of patch clamp devices to manufacture structures from PDMS (elastomeric polymer) as an alternative to glass (See the abstract).

In view of this teaching, it would have been obvious to one of ordinary skill in the art at the time the invention was made to construct the substrate of the primary references out of PDMS for the known and expected results of providing an alternative means recognized in the art to achieve the same result, providing a substrate employed in a patch clamp device. PDMS would be preferred over glass in view of its low dielectric loss and ease of manufacture.

Art Unit: 1744

11. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Baumann et al.(US 6,368,851) or Stett et al. (US 2003/0153067 or WO 02/03058) in view of Maher et al.(US 6,686,193).

The references of Baumann et al. and Stett et al. have been discussed above.

While both the references of Baumann et al. and Stett et al. disclose the use of electrodes or conducting elements, the references are silent with respect to the use of a carbon material.

The reference of Maher et al. discloses that it is known in the art to employ carbon based electrically conductive material in devices wherein cells are exposed to the conductive material (See column 15, lines 8-30).

In view of this teaching, it would have been obvious to one of ordinary skill in the art to manufacture the electrical conducting members or elements of the primary references with carbon materials for the known and expected result of providing an art recognized material that can be exposed to cells. Use of any of the materials, including carbon, as disclosed by the reference of Maher et al. would be preferred in view of their low cost and reduced toxicity to the cells in the device.

### ***Double Patenting***

12. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re*



Art Unit: 1744

*Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

13. Claims 1-8, 11-18, 21-30, 87-89, 93-95, 97-101 and 109-116 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 31-37 and 62 of copending Application No. 10/688,794. Although the conflicting claims are not identical, they are not patentably distinct from each other because.

Claims 1-8, 11-18, 21-30, 87-89, 93-95, 97-101 and 109-116 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 31-37 and 62 of copending Application No. 10/688,794. An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim not is patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985). Although the conflicting claims are not identical, they are not patentably distinct from each other because Claims 1-8, 11-18, 21-30, 87-89, 93-95, 97-101 and 109-116 are generic to all that is recited in claims 31-37 and 62 of copending Application No. 10/688,794. That is, claims 31-37 and 62 of copending Application No. 10/688,794 fall entirely within the scope of Claims 1-8, 11-18, 21-30, 87-89, 93-95, 97-101 and 109-116 or, in other words, Claims 1-8, 11-

Art Unit: 1744

18, 21-30, 87-89, 93-95, 97-101 and 109-116 are anticipated by claims 31-37 and 62 of copending Application No. 10/688,794.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

***Response to Arguments***

14. With respect to the objection to the drawings, Applicants comment (See page 9 of the response filed 5/22/2007) that amended drawings will be submitted.

In response, the objection will be maintained until corrected drawings meeting the deficiencies are submitted and approved.

15. With respect to the 35 USC 112 rejections of record, while Applicants have responded to the previous rejections (See page 9 of the response filed 5/22/2007), new grounds of rejection have been made in response to the amended claim language added to the claims.

16. With respect to the rejection of Claims 1-6, 9-18, 20-30, 87-89, 93-95 and 97-101 under 35 U.S.C. 102(a) or (e) as being anticipated by Baumann et al.(US 6,368,851), Applicants argue (See pages 10-11 of the response filed 5/22/2007) that the rejection is improper because the reference of Baumann et al. fails to disclose a device that includes or encompasses “at least one cell chamber, at least one non-planar element exposed to fluid flow from a fluid source, and wherein the nonplanar element is an integral part of the substantially planar substrate”.

In response, the Examiner maintains that the reference of Baumann et al. meets all of the claim limitations. Specifically, the reference of Baumann et al. discloses at least one cell chamber (See Figure 18) and at least one non-planar element (20) that is integral with substrate (4) and can be exposed to a fluid source (See column 16, line 67, to column 17, line 2).

17. With respect to the rejection of Claims 1-3, 5, 9-19, 21-23, 25, 27-30, 87-89, 93-95 and 97-101 under 35 U.S.C. 102 (e) as being anticipated by Stett et al. (US 003/0153067) and Claims 1-3, 5, 9-19, 21-23, 25, 27-30, 87-89, 93-95 and 97-101 under 35 U.S.C. 102(a) as being anticipated by Stett et al. (WO 02/03058), Applicants argue (See pages 11-12 of the response filed 5/22/2007) that the rejection is improper because the non-planar element of Stett et al. is not integral with the substrate.

In response, the rejection has been changed from 35 USC 102 to 35 USC 103 to address the newly recited integral limitation in the independent claims. The fact that a structural element is integral rather than separable is not a patentable distinction. Note "that the use of a one piece construction instead of the structure disclosed in [the prior art] would be merely a matter of obvious engineering choice." In re Larson, 340 F.2d 965, 968, 144 USPQ 347, 349 (CCPA 1965).

18. With respect to the rejection of Claim 7 under 35 U.S.C. 103(a) as being unpatentable over Baumann et al. (US 6,368,851) or Stett et al. (US 2003/0153067 or WO 02/03058) in view of Klemic et al. (Biosensor and Bioelectronics) and Claim 8 under 35 U.S.C. 103(a) as being unpatentable over Baumann et al. (US 6,368,851) or Stett et al. (US 2003/0153067 or WO

Art Unit: 1744

02/03058) in view of Maher et al.(US 6,686,193), Applicants argue (See pages 12-13 of the response filed 5/22/2007) that the rejections are improper for the same deficiencies set forth with respect to the independent claims.

In response, the Examiner maintains that the rejections are proper for the same reasons as set forth immediately above.

19. With respect to the obviousness-type double patenting rejection of record, Applicants comment (See page 13 of the response filed 5/22/2007) that a terminal disclaimer will be filed.

In response, the rejection will be maintained until a proper disclaimer is filed and made of record.

### *Conclusion*

20. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

Art Unit: 1744

however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

21. Any inquiry concerning this communication or earlier communications from the examiner should be directed to William H. Beisner whose telephone number is 571-272-1269. The examiner can normally be reached on Tues. to Fri. and alt. Mon. from 6:15am to 3:45pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gladys J. Corcoran can be reached on 571-272-1214. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/William H. Beisner/  
Primary Examiner  
Art Unit 1744

WHB